MAY 0 8 2002

K012979

510(k) Summary

1. Submitter: **Medical Device Services, Inc.** (MDS)
144 West Bringham Road, Building E
St. George, UT 84790
Tel: 435-652-3073
Fax: 435-652-3087

2. Contact: Ron Eames, President
Medical Device Services, Inc.

3. Date prepared: August 31, 2001

4. Device trade name: Sleeve, Limb, Compressible

Common name: Compressible Sleeve

5. Predicate device: Kendall Model 6325 SCD Sequential Compression System
K942664

6. Description: The compressible sleeve is a garment used for compressing patient's lower limbs by inflation with air to aid the blood flow back towards the heart to prevent deep vein thrombosis (DVT) in patients at risk. The inflatable sleeve consists of inflatable air bladders and tubing, and are connected to the OEM equipment using specific connector(s). The MDS reprocessed sleeve pair is cleaned, inspected and sterilized in sealed individual pouches and returned to the originating hospital.

7. Intended Use:
The sequential compression sleeve is designed to increase venous blood flow in the non-ambulatory patient in order to help prevent deep vein thrombosis and pulmonary embolism.

8. Technological comparison to predicate device:
The technological characteristics of the reprocessed sleeves are substantially equivalent (in materials, design, and intended use) to the sleeves as originally distributed.

9. Noncritical test summary:
Comparative bench testing of new Kendall SCD Sequential Compression Device to reprocessed Kendall SCD Sequential Compression Devices was conducted at Medical Device Services, Inc. The data indicates no significant difference in functional and safety characteristics between new and reprocessed devices.

10. Conclusion: The reprocessed Kendall SCD is substantially equivalent to the legally marketed predicate device.

Note: The 510(k) Summary has been modified.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 0 8 2002

Mr. Ron Eames
President
Medical Devices Services, Inc.
144 West Bringham Road, Building E
St. George, UT 84790

Re: K012979
Trade Name: Medical Devices Services Reprocessed Compressible Lim Sleeve
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II (two)
Product Code: JOW
Dated: March 20, 2002
Received: March 21, 2002

Dear Mr. Eames:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

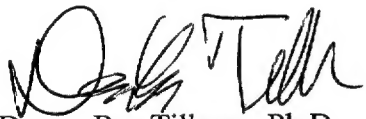
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

PREMARKET NOTIFICATION
INDICATIONS FOR USE STATEMENT

(As required by ODE for all 510(k) received after Jan. 1, 1996.)

510(k) Number:

Device Name: Compressible limb sleeve

Indications For Use:

The sequential compression sleeve is designed to increase venous blood flow in the non-ambulatory patient in order to help prevent deep vein thrombosis and pulmonary embolism.

(Do not write below this line. Continue on another page if needed.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K012979

Prescription Use X or Over-The-Counter Use ____
(Per 21 CFR 801.109)